510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k043443

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Human Chorionic Gonadotrophin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

One Step HCG Urine Pregnancy Test

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1155, Human chorionic gonadotropin (HCG) test system

2. Classification:
   Class II

3. Product code:
   LCX, kit, test, pregnancy, hCG, over the counter
   JHI, radioimmunoassay, human chorionic gonadotropin

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The Guangzhou Wondfo Biotech Co., Ltd. One Step HCG Urine Pregnancy Test

is intended for non-professional, over-the-counter use and for professional and laboratory use for the qualitative identification of the elevated levels of human Chorionic Gonadotrophin (hCG) in urine to aid in the determination of pregnancy.

2. Indication(s) for use:

   See Intended Use above.

3. Special conditions for use statement(s):

   For over-the-counter and professional use

4. Special instrument requirements:

   None

I. Device Description:

The One Step HCG Urine Pregnancy Test will be sold in three formats: cassette, test strip, and midstream. The test strip and midstream kits consist of one test device and a package insert. The cassette kit consists of one test device and a disposable plastic dropper, and a package insert. Each test device contains mouse monoclonal anti-α-hCG antibody coated membrane and a pad containing mouse monoclonal anti-β-hCG antibody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   WHPM One-Step Pregnancy Test
   Acon Quick-Check II Home pregnancy Test
   Acon Quick-Check II Home pregnancy Test Strip
   Accutest hCG-Combo
   E.P.T. Pregnancy Test
   Unimark Home Pregnancy Test Device
   Good Morning Test

2. Predicate 510(k) number(s):
   k041273
   k032510
   k033041
   k032987
   k033658
   k032992
   k031798

3. Comparison with predicate:

The device and the predicate devices share the same intended use and test methodology.

Similarities		
Item	Device	Predicate
Formats Available	Strip, Cassette, Midstream	Strip, Cassette, Midstream
Specimen type	Urine	Urine
Antibodies	Goat, mouse	Goat, mouse
Cutoff	25 mIU/mL	25 mIU/mL
Storage Temperature	4 – 30 ˚C	4 – 30 ˚C

Differences		
Item	Device	Predicate
Read time	3 – 5 minutes	3 – 10 minues

K. Standard/Guidance Document Referenced (if applicable):

None

L. Test Principle:

The device is a solid phase, sandwiched immunochromatographic assay. Users are instructed to soak the absorbent pad with urine. The urine will migrate via capillary action toward the result and control window. If hCG is present in the urine it reacts with an anti-HCG-colloidal gold particle conjugate to form a colored line in the test region of the strip. A colored line in the control region of the device indicates adequate sample volume and capillary action. Absence of a colored line in the control region is an indication of an invalid result. Users are instructed to read the device at 5 minutes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

Precision of the device was evaluating by testing negative urine samples spiked with hCG (to 500 IU/ml, 200 IU/ml, 100 IU/ml, 5 IU/ml, 1000 mIU/ml, 500 mIU/ml, 100 mIU/ml, 50 mIU/mL, 25 mIU/ml, 20 mIU/ml, 15 mIU/ml, and 10 mIU/ml hCG), one positive urine sample (containing 29 mIU/mL hCG), and one negative urine sample 10 times with each of three lots of product (total n/sample = 30). The results are summarized below:

hCG	Tested	Lot I	Lot II	Lot III
500 IU/mL	1	-	-	-
	2	-	-	-
	3	-	-	-
	4	-	-	-
	5	-	-	-
	6	-	-	-
	7	-	-	-
	8	-	-	-
	9	-	-	-
	10	-	-	-
200 IU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	-	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	-	+	-
	9	+	+	+
	10	+	+	+
100 IU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+
5 IU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+

hCG	Tested	Lot I	Lot II	Lot III
50 mIU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+
Positive (29 mIU/mL)	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+
25 mIU/ml	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+
20 mIU/ml	1	-	-	-
	2	+	-	-
	3	-	-	-
	4	-	-	-
	5	-	-	-
	6	-	-	-
	7	-	-	-
	8	-	-	-
	9	-	-	-
	10	-	-	-

hCG	*Tested*	*Lot I*	*Lot II*	*Lot III*
1000 mIU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+
500 mIU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+
100 mIU/mL	1	+	+	+
	2	+	+	+
	3	+	+	+
	4	+	+	+
	5	+	+	+
	6	+	+	+
	7	+	+	+
	8	+	+	+
	9	+	+	+
	10	+	+	+

hCG	*Tested*	*Lot I*	*Lot II*	*Lot III*
15 mIU/ml	1	-	-	-
	2	-	-	-
	3	-	-	-
	4	-	-	-
	5	-	-	-
	6	-	-	-
	7	-	-	-
	8	-	-	-
	9	-	-	-
	10	-	-	-
10 mIU/ml	1	-	-	-
	2	-	-	-
	3	-	-	-
	4	-	-	-
	5	-	-	-
	6	-	-	-
	7	-	-	-
	8	-	-	-
	9	-	-	-
	10	-	-	-
Negative (0 mIU/mL)	1	-	-	-
	2	-	-	-
	3	-	-	-
	4	-	-	-
	5	-	-	-
	6	-	-	-
	7	-	-	-
	8	-	-	-
	9	-	-	-
	10	-	-	-

b. Linearity/assay reportable range:

High dose hook effect was evaluated by spiking increasing hCG concentrations into negative urine samples and evaluating the test result lines. The sponsor concludes that the test can be used for samples up to 100,000 mIU/mL. Results are summarized below (units = mIU/mL).

hCG concentration	**Test Result**
12.5	+/-
25	+
100	++

hCG concentration	*Test Result*
500	+++
1000	+++
5000	++
25,000	+
100,000	+
200,000	+/-
500,000	-

The sponsor repeated the high dose hook effect evaluation during the precision studies and the following results were obtained (see expanded preision data above):

hCG concentration	**Test result**
10 mIU/ml	-
15 mIU/ml	-
20 mIU/ml	-/+
25 mIU/ml	+
100 mIU/ml	++
500 mIU/ml	+++
1000 mIU/ml	+++
5 IU/ml	++
25 IU/ml	+
100 IU/ml	+
200 IU/ml	-/+
500 IU/ml	-

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

This device is traceable to the WHO 3rd International standard.

Protocols and acceptance criteria were descried for stability testing including validation of shipping stability.

d. Detection limit:

The sensitivity of the device was tested by spiking 60 negative urine samples with varying concentrations of hCG from a standard sample. Results are summarized below (units = mIU/mL).

Concentration	**Positive**	**Negative**	**Total n**
0	0	5	5
12.5	0	5	5
18.75	0	5	5
25	29	1	30
50	10	0	10

Concentration	*Positive*	*Negative*	*Total n*
100	5	0	5
Total	**44**	**16**	**60**

All results (100%) below 18.75 mIU/mL tested negative. Fourteen (14) out of 15 samples (98.8%) at 25 mIU/mL tested positive. All samples (100%) above 50 mIU/mL tested positive. The sponsor claims a cutoff for positive of 25 mIU/mL.

e. Analytical specificity:

To evaluate potential cross-reactivity with similar endogenous compounds, 90 negative urine samples were divided into 3 aliquots each and were supplemented with increasing concentrations of luteinizing hormone (hLH), follicle stimulating hormone (hFSH), or thyroid stimulating hormone (hTSH). Results were read in 5 minutes. Results are summarized below (total n per concentration = 30, units = mIU/mL).

(mIU/mL)		**Lot I**		**Lot II**		**Lot III**	
		+	**-**	**+**	**-**	**+**	**-**
hLH	**100**	0	30	0	30	0	30
	300	0	30	0	30	0	30
	500	1	29	1	29	0	30
hFSH	**100**	0	30	0	30	0	30
	300	0	30	0	30	0	30
	500	0	30	1	29	0	30
hTSH	**750**	0	30	0	30	0	30
	1000	0	30	0	30	0	30
	1250	0	30	0	30	1	29

The sponsor claims that there is no interference at 300 mIU/mL hLH, 300 mIU/mL hFSH, or 1000 mIU/mL hTSH.

To evaluate the potential for interference by certain exogenous compounds, samples with varying hCG concentrations were spiked with potential interferants and tested. No interferences were observed at the concentrations tested. Results are summarized below (units = mIU/mL).

Substance	0 mIU/mL hCG	25 mIU/mL hCG	50 mIU/mL hCG
Acetominophen 20 mg/dL	-	+	+
Acetylsalicylic acid 20 mg/dL	-	+	+
Ascorbic acid 20 mg/dL	-	+	+
Atropine 20 mg/dL	-	+	+
Caffeine 20 mg/dL	-	+	+
Centesic acid 20 mg/dL	-	+	+
Glucose 2 g/dL	-	+	+
Hemoglobin 20 mg/dL	-	+	+

Substance	*0 mIU/mL hCG*	*25 mIU/mL hCG*	*50 mIU/mL hCG*
Tetracycline 20 mg/dL	-	+	+
Ampicillin 20 mg/dL	-	+	+
Albumin 20 mg/dL	-	+	+

The sponsor evaluated the device and found that samples with pH 4 – 9 or with densities between 1.000 – 1.050 were not adversely affected and produced the expected results.

f. Assay cut-off:

The cutoff for a positive test is 25 mIU/mL. See Detection Limit section above.

2. Comparison studies:

a. Method comparison with predicate device:

The device and the predicate were used to evaluate 619 urine samples. A portion of the samples (245) were obtained from pregnant women (aged 20 – 35). The remainders (374) were obtained randomly from apparently healthy people. These samples were tested using all three strip formats of the device. Results are summarized below:

STRIP	**Device**		**Predicate**	
	Positive	**Negative**	**Positive**	**Negative**
Pregnant	243	2	244	1
Other	1	373	0	374

CASSETTE	**Device**		**Predicate**	
	Positive	**Negative**	**Positive**	**Negative**
Pregnant	243	2	243	2
Other	1	373	1	373

MIDSTREAM	**Device**		**Predicate**	
	Positive	**Negative**	**Positive**	**Negative**
Pregnant	243	2	243	2
Other	1	373	0	374

b. Matrix comparison:

Not applicable.

3. Clinical studies:
   a. Clinical Sensitivity:

Urine samples from 100 patients who were clinically confirmed to be pregnant and 166 randomly chosen, non-pregnant female patients were tested with the strip form of the device. All 100 samples from pregnant women tested positive with the device, and all 166 non-pregnant women tested negative.

To test the useability of the strip format of the device, 87 women completed self-tests and recorded the results. The women also collected urine samples for testing at a hospital lab by a healthcare professional. The same women were clinically followed and confirmed "pregnant" or "not pregnant." Results are summarized below:

	Device		
	Positive	Negative	**Total**
Positive	50	1	**51**
Negative	0	36	**36**
Total	50	37	**87**

To test the useability of the cassette format of the device, 54 women completed self-tests and recorded the results. The women also collected urine samples for testing at a hospital lab by a healthcare professional. The same women were clinically followed and confirmed "pregnant" or "not pregnant." Results are summarized below:

	Device		
	Positive	Negative	**Total**
Positive	31	0	**31**
Negative	0	23	**23**
Total	31	23	**54**

To test the useability of the midstream format of the device, 48 women completed self-tests and recorded the results. The women also collected urine samples for testing at a hospital lab by a healthcare professional. The same women were clinically followed and confirmed "pregnant" or "not pregnant." Results are summarized below:

	Device		
	Positive	Negative	**Total**
Positive	28	0	**28**
Negative	0	20	**20**
Total	28	20	**48**

*b. Clinical specificity**:***

See above

c. Other clinical supportive data (when a. and b. are not applicable):

Patients (n = 189) who participated in the lay-user studies conducted testing using only the package insert as a guide. In addition, each patient was given a questionnaire to

assess the readability of the labeling. The results of the questionnaire showed that the consumers found the test easy to use and that they did not have trouble understanding the labeling and interpreting the results.

4. Clinical cut-off**:**
   Not applicable

5. Expected values/Reference range:

All healthy non-pregnant females should test negative for hCG. Although hCG levels vary in normal newly pregnant women, the sponsor claims that the test should detect hCG levels one day after the woman's missed menstrual cycle.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.